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| APPLICATION NO  | . F  | ILING DATE  | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|------|-------------|----------------------|-------------------------|------------------|
| 09/431,008  |      | 11/01/1999  | JEFFREY H. BURBANK   | 17742-000630            | 8128             |
| 20350   | 7590 | 05/22/2002  |                      |                         |                  |
|   |      | TOWNSEND AN | EXAMINER             |                         |                  |
| TWO EMBARCADERO CENTER EIGHTH FLOOR SAN ERANGISCO, CA. 04111 2824 |      |             |                      | THANH, LOAN H           |                  |
| SAN FRANCISCO, CA 94111-3834                                      |      |             |                      | ART UNIT                | PAPER NUMBER     |
|   |      |             | •                    | 3763                    |                  |
|   |      |             |                      | DATE MAILED: 05/22/2002 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |  | Application No.                 | Applicant(s)  |  |  |  |
|---|--|---------------------------------|---|--|--|--|
|   |  | 09/431,008                      | BURBANK ET AL.                                      |  |  |  |
|   | Office Action Summary  | Examiner                        | Art Unit  |  |  |  |
|   |  | LoAn H. Thanh                   | 3763  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |  |                                 |   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status |  |                                 |   |  |  |  |
| 1)  | Responsive to communication(s) filed on 28 J   | anuarv 2002 .                   |   |  |  |  |
| 2a)□  | · · · · · · · · · · · · · · · · · · ·  | s action is non-final.          |   |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  |  |                                 |   |  |  |  |
| Disposition of Claims   |  |                                 |   |  |  |  |
| 4)⊠ Claim(s) <u>1-11</u> is/are pending in the application.   |  |                                 |   |  |  |  |
| 4a) Of the above claim(s) <u>8-11</u> is/are withdrawn from consideration.  |  |                                 |   |  |  |  |
| 5) Claim(s) is/are allowed.   |  |                                 |   |  |  |  |
| 6)⊠ Claim(s) <u>1-7</u> is/are rejected.  |  |                                 |   |  |  |  |
| 7)  | Claim(s) is/are objected to.   |                                 |   |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.  Application Papers   |  |                                 |   |  |  |  |
| 9)⊠ The specification is objected to by the Examiner.   |  |                                 |   |  |  |  |
| 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.  |  |                                 |   |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |                                 |   |  |  |  |
| 11)∐ T  | he proposed drawing correction filed on  | is: a) ☐ approved b) ☐ disappro | ved by the Examiner.                                |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |  |                                 |   |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |  |                                 |   |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |  |                                 |   |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |  |                                 |   |  |  |  |
| a) All b) Some * c) None of:  |  |                                 |   |  |  |  |
|   | 1. Certified copies of the priority documents have been received.  |                                 |   |  |  |  |
| :   | 2. Certified copies of the priority documents have been received in Application No   |                                 |   |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |  |                                 |   |  |  |  |
| 14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).   |  |                                 |   |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received.  15) ☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Attachment(s)  |  |                                 |   |  |  |  |
| 2) Notice   | of References Cited (PTO-892) of Draftsperson's Patent Drawing Review (PTO-948) ation Disclosure Statement(s) (PTO-1449) Paper No(s) 5 | 5) Notice of Informal P         | (PTO-413) Paper No(s)  Patent Application (PTO-152) |  |  |  |

U.S. Patent and Trademark Offic PTO-326 (Rev. 04-01)

#### **DETAILED ACTION**

#### Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 9 is acknowledged.

Claims 8-11 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

An action on the merits now follows.

### **Drawings**

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tapered bore must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Although a bore is shown, no tapering of the bore is shown.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### Specification

The disclosure is objected to because of the following informalities:

Applicant is requested to update the status of the parent case (08/942,990).

Appropriate correction is required.

The lengthy specification has been checked but not been checked to the extent necessary to determine the presence of all possible minor errors.

Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is vague and indefinite because it is unclear whether the valve lock should be refer back to "the latch" or whether the pair of balls is in addition to the latch of the valve lock.

Claim 6 is indefinite because "the valve" lacks proper antecedent basis in line 1. Applicant has support for a valve assembly. Further it is recommended that applicant writes "the group consisting of ...and..." for a proper markush claim or in the alternative language using "or". The "and" language makes it unclear .

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors

Protection Act of 1999 (AIPA) do not apply to the examination of this application
as the application being examined was not (1) filed on or after November 29,
2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this
application is examined under 35 U.S.C. 102(e) prior to the amendment by the
AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2,6 rejected under 35 U.S.C. 102(e) as being anticipated by Flaherty ( U.S. Patent No. 5,702,363).

See figs. 1-2 of Flaherty, specifically 2. Flaherty discloses an implantable port comprising a base (2, 2",2"") having a passage for receiving an access tube (240), a valve assembly (246) being a duckbill valve and a valve lock having a latch which shifts position to lock the valve assembly open. The valve lock is considered to be element 220' and 233, 248. The valve lock is considered to latch onto to the duckbill valve by shifting position to maintain the duckbill valve open when the access tube is inserted such that the duckbill valve is opened in

response to the movement of the access tube/needle and also the latch. The reference is capable of performing the functional limitations as claimed.

Claims 1-3,6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ensminger et al. (U.S. Patent No. 5,476,451).

Ensminger et al. disclose an implantable port having a base having a passage See figs. 22-25 cols 14. Ensminger et al. show a valve assembly 296, having a bore (297) which receives an access tube (304) and is capable of being open in response to movement of the access tube (304). Ensminger et al. further show a valve lock (288) having a latch which comprises at least one space-filling element which is displaced from the passage into a receptacle (302). See fig. 23 and 25. With respect to the functional language, the device of Ensminger et al. is capable of performing the function. Although Ensminger et al. discloses the levers 290 and 290' to be manually moved for the access tube (304) to be inserted, it is the Examiner's position that with the beveled end of the tube (304), would be capable of insertion into the bore such that the space filling element is shifted into the receptacle and remains there so long as the access tube stays in the bore.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

<sup>(</sup>a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 7 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Flaherty (U.S. Patent No. 5,702,363) in view of White (U.S. Patent No. 4,393,882).

Flaherty discloses the invention as substantially claimed. See above.

Flaherty further shows a tapered bore at the proximal end of the valve lock (220', 233,248). Fig. 1 shows a better view of the valve lock when there is no access tube. The tapered is considered to be the proximal end to the points of contact with the access tube at 233. Flaherty teaches the seal element (233) for engaging the access tube to prevent leakage. See col. 7, 13-21. In the event that applicant is not convinced that Flaherty anticipates the tapered bore, then it would have been obvious to modify the bore of Flaherty as taught by White (

White teaches a tube in a tapered bore of a fluid device for sealing such that there's no leakage. See fig. 2 and 3.) in order to provide a good seal to prevent leakage.

# Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims, 112-113, 123-124 of U.S. Patent No. 6,007,516. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are a broader recitation of the invention than that of the issued patent, including all of the same limitations. The claims of the application claim an implantable port comprising a base having a passage, a valve assembly in the base having a bore wherein the valve assembly opens in response to insertion of the access tube, and a valve lock having a latch which shifts to lock the valve assembly open. The patent claims recite an implantable port comprising a base having a passage, a valve assembly in the base having a bore wherein the valve assembly opens in response to insertion of the access tube, and a pair of balls disposed between the passage and the bore which are spring –biased to close against and lock the access tube. Since a broad interpretation of the latch includes the pair of balls, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the 6,007,516 patent.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is

(703) 305-0038. The examiner can normally be reached on Monday - alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

LoAn H. Thanh

Examiner Art Unit 3763

LT May 17, 2002